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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,866	04/16/2004	Michael A. Spohn	CV/04-001	8191

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EXAMINER	
MACNEILL, ELIZABETH	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,866	SPOHN ET AL.	
	Examiner	Art Unit	
	Elizabeth R. MacNeill	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49 and 83-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49 and 83-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 17-25 are rejoined in view of applicant's arguments submitted 27 March 2007.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 8-10, 12-16, 26-30,36-40,42,83-88,90-103, 109-113, and 115 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwietzer, Jr et al (US 5,584,671).

Regarding claims 1 and 26, Schweitzer Jr et al teaches an injector system comprising; a source of injection fluid; a pump device (16); a fluid path set (20,21) disposed between the source of injection fluid and the pump device, and comprising a multi-position valve (19); a fluid control device (26) operatively associated with the fluid path set and comprising a valve actuator (14) adapted to operate the multi-position valve, the valve actuator adapted to close the multi-position valve to isolate the pump device from a patient and stop flow of the injection fluid to the patient at substantially any pressure or flow rate generated by the pump device for delivering a sharp bolus of the injection fluid to the patient.

Regarding claim 2, the valve actuator is further adapted to selectively place the pump device in fluid communication with the source of injection fluid for supplying the injection fluid to the pump device.

Regarding claims 3 and 27, the valve actuator comprises a position indicator (knob) indicating a position of the multi-position valve.

Regarding claims 4 and 28 the valve actuator comprises a sensor (42) indicating presence of the multi-position valve in the valve actuator.

Regarding claims 5 and 29 the valve actuator comprises a retainer (45) for removably supporting the multi-position valve.

Regarding claims 6,10,30 and 40 the fluid path set comprises a drip chamber (23) and the fluid control device comprises a fluid level sensing mechanism (drip sensors, not shown) operatively associated with the drip chamber for sensing the injection fluid level in the drip chamber.

Regarding claim 8, the pump device comprises a powered injector (via 25).

Regarding claim 9, the device further comprises a source of medical fluid (11) associated with the fluid path set; and a pump (16) operatively associated with the source of medical fluid for supplying the medical fluid to the patient via the fluid path set.

Regarding claims 12 and 37 the device further comprises a shut-off valve (19) associated with the pump for stopping flow of the medical fluid to the patient.

Regarding claims 13 and 38 the shut-off comprises an automated pinch valve.

Regarding claims 14,36 and 39 the pump comprises a peristaltic pump (16).

Regarding claims 15 and 42 device further comprises guides (Fig 1) for securing the fluid path set in association with the pump.

Regarding claim 16, the device further comprises a hand held control device (26) for controlling the flow rate of the injection fluid from the pump device.

4. Claims 83-85, 87,88,89-91,93,97-99,102,109,114, and 115 are rejected under 35 U.S.C. 102(b) as being anticipated by Duchon et al (US 6,099,502).

Duchon teaches a source of injection fluid (22, 50, 52), a pump (18/20), a fluid path set (42, 90, 28, etc), a fluid control device (multiposition valve 34) with a valve actuator (control knob on 34). Duchon et al teaches a powered infusion device with an air column detector (552) disposed along a fluid path (588) with a retaining device (627,628), and a base (540) (Fig 19). Handheld control device (14).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7,11,21-25,41,43-49,89, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweitzer Jr et al in view of Duchon et al (US 6,099,502).

Schweitzer Jr et al teaches the limitations of claims 1 and 26 as above, but fails to teach the inclusion of an air detector assembly. Duchon et al teaches a powered infusion device with an air column detector (552) disposed along a fluid path (588) with a

retaining device (627,628), and a base (540) (Fig 19). To use a clear plastic would have been a matter of obvious design choice.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the air in line detector and retaining member set of Duchon with the injector of Schweitzer Jr in order to prevent the injection of air bubbles into the patient.

7. Claims 31-35, 17-20, and 104-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweitzer Jr et al as applied to claims 1 and 26 above, and further in view of Sunderland (US 5,057,081).

Schweitzer Jr et al teaches the limitations of claims 1 and 26, but does not teach the particulars of the drip chamber. Sunderland teaches a drip chamber for use in a peristaltic infusion device wherein the drip chamber (42) includes a body (48) with a longitudinally extending projection (37), an optical fluid level sensor (43), and a drip chamber support (39). The use of two drip chambers would be an obvious duplication of parts (*St Regis Paper Co v. Bemis Co.,* 193 USPQ 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the drip chamber and support of Sunderland in order to securely lock the drip chamber to the pump housing and ensure the drip chamber is in communication with the optical sensors.

Response to Arguments

8. Applicant's arguments filed 27 March 2007 have been fully considered but they are not persuasive.

Regarding Schweitzer, applicant has argued that because the valve is upstream of the pump it cannot isolate the pump from the patient. This is not persuasive because the valve stops the flow of fluid to the pump and therefore the pump is not able to supply any more fluid to the patient, thus isolating the pump. The upstream and downstream language the applicant is arguing is not in the claims.

Regarding Duchon, applicant has argued that a check valve is not a multiposition valve. The valve has more than one position (open, closed) and is therefore multiposition. Second, the claims do not require that the valve is automatically actuated. A valve actuator, as claimed, could simply be the knob on the three-way stop cock valve. Applicant has presented no arguments relating to the air detector or drip chambers of Duchon and Sutherland.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elizabeth MacNeill
4/12/07

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons

Related Applications	
Application No.	Published Document
/EM/ 10/818,748	2004/0242996
10/818,477	2004/0254533
10/326,582	2004/0122369
10/237,139	6,866,654
09/982,518	7,094,216

Any references identified during the prosecution of the foregoing applications that are not already of record in this application are also identified on accompanying Form PTO/SB/08A.

Pursuant to 37 C.F.R. §1.97(c)(2), Applicants submit herewith the required petition fee in the amount of $180.00 for submission of this Supplemental Information Disclosure Statement which is being submitted after issuance of a first Office Action but before the mailing date of a final Office Action. The Commissioner for Patents is hereby authorized to charge any additional fees which may be required to Deposit Account No. 13-2530.

/Elizabeth Macneill/

04/12/2007

Respectfully submitted,

By _____

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